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Critical Elements for Certification

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16. ABSTRACT

The Microbiology Subcommittee of the Drinking Water Laboratory Certification Implementation Work Group has revised Chapter V of the Manual for the Interim Certification of Laboratories Involved in Analyzing Public Drinking Water Supplies. The technical criteria for Chapter V are divided into two sections, Critical Elements and Recommended Practices. Only the Critical Elements will be used to determine certification status. Critical Elements and Recommended Practices are described and discussed.

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CRITICAL ELEMENTS FOR CERTIFICATION

Harry D. Nash, Chairman, Microbiology Sub-Committee
Microbiological Treatment Branch
Drinking Water Research Division
Municipal Environmental Research Laboratory
U.S. Environmental Protection Agency
26 West St. Clair Street
Cincinnati, Ohio 45268

The Drinking Water Laboratory Certification Implementation (DWLCI) Work Group established three Sub-Committees, one for each of three technical disciplines, microbiology, chemistry, and radiochemistry. Each sub-committee functions as a technical advisory group responsible to the DWLCI Work Group. One of the primary functions of each group was to revise the specific technical chapter of the "Manual for the Interim Certification of Laboratories Involved in Analyzing Public Water Supplies". During the revision, the sub-committee incorporated suggestions and recommendations which were received as a result of an extensive review program of the Manual for Interim Certification. These suggestions and recommendations were received from all EPA Regions, States, municipalities, and science advisory groups. As the revision progressed, drafts were again submitted for extensive review and all additional comments were considered and used to develop the final draft submitted to the DWLCI Work Group for approval prior to final approval by the Office of Drinking Water.

Basically the revision was one of format to separate Critical Elements for Certification from Recommended Practices, to define quality control items and to clarify some of the existing critical element items. A sincere effort was made not to create additional critical elements and certainly not to change recommended practices to critical elements. The format revision was accepted by the reviewers and was considered to be a substantial improvement. The chapter is now divided into three sections: (1) Critical Elements for Certification, those items essential to the proper application of approved methodology which will determine laboratory certification approval; (2) Recommended Practices, those items providing guidance for good overall laboratory practice; and (3) A Sample Evaluation Form which can be used during an on-site evaluation. The sample form is to aid the evaluator in conducting a systematic on-site evaluation and lists only those items presented in the section on Critical Elements for Certification. The sections on Critical Elements and Recommended Practices are subdivided into nine categories: Personnel; Laboratory Facilities; Laboratory Equipment, Supplies, and Materials; General Laboratory Practices; Analytical Methodology; Sample Collection, Handling, and Preservation; Quality Assurance Program; Data Reporting; and Action Response to Laboratory Results. Of the two major sections, Critical Elements for Certification and Recommended Practices, only the Critical Elements for Certification are to be used to determine laboratory certification approval. Furthermore, critical elements

are used to determine certification only if the laboratory uses the equipment required for the methodology or has the final delegated responsibility relating to any critical element. Critical elements relative to the membrane filter procedure would not be applicable to laboratories conducting only the multiple tube fermentation procedure. Also, the critical element referring to sample collectors being trained in sampling procedures would not be used to determine certification approval if the laboratory were not delegated the responsibility of training sample collectors.

The number and extent of detail of the critical elements in the chapter on microbiology are greater than those set forth in the chemistry chapter. Standard samples having true values of bacterial densities which can consistently be recovered using the best methodology are not available to the microbiologist. Performance evaluation and quality control samples for microbiology serve to substantiate tne correct application of the methodology to the analysis. Therefore, expansion of the number and detail of the microbiological critical elements was necessary to insure that the most accurate and valid data are obtained by the analytical method applied to the analysis.

It is important to understand that the intent of the critical elements was not to impose a burden upon laboratories by increasing the work load. Many of the quality control items are being and have been conducted by many of the laboratories in the past. However, in many cases, documentation of quality control measures has been inadequate and must be updated. The need for some improved documentation relates to pH meter standardization, media pH, calibration of balances, sterility of materials and autoclaving procedures. The critical elements relating to these items are minimal but are considered necessary to assure that the method will provide valid data.

All quality control measures relating to Critical Elements for Certification are designated by the capital letters "QC" and require documentation. Quality control items relating to laboratory equipment and supplies are:

1. Standardizaton of pH meters using a pH 7.0 standard buffer. Many reviewers recommended the use of three standard buffers, pH 4.0, 7.0 and 10. This appears excessive to include in the critical elements; however, use of these standard buffers would not be discouraged.

2. Calibration of balances monthly using Class S or S-1 reference weights. Non-reference weights may be used if calibrated annually with Class S or S-1 reference weights. This does provide an option as to the purchase of Class S or S-1 reference weights.

3. Calibration of glass/mercury thermometers annually against a reference NBS thermometer at the temperature for use.

4. Recording the temperatures of incubators on the days in use, at least twice per day with each reading separated by at least four hours.

5. Recording the date and sterilization time and temperature for each sterilization procedure.

Quality Control items relating to General Laboratory practices are:

1. Confirming sterility of sample bottles using a non-selective broth.

2. Testing the quality of laboratory pure water which includes conductivity, total chlorine residual and performance of the test for bacteriological quality of distilled water.

3. Checking sterility of rinse water using a non-selective broth.

4. Conducting the Inhibitory Residue Test to insure that lab ware washing compounds do not leave a toxic residue.

5. Recording media prepared: the date of preparation, type of medium, lot number, sterilization time and temperature, final pH and technicians initials.

6. Conducting MF sterility checks at the end of each filtration series.

It must be emphasized that these quality control items are minimal and all laboratories are encouraged to expand quality control measures as needs are recognized. Also, quality control becomes ineffectual unless it is adequately documented.

Critical elements relating to time limits for autoclaving of materials were intentionally written as minimal times for sterilization of sample bottles, glassware, dilution water, rinse water and contaminated test materials. Sterilization times will vary depending upon volume, container size and load size. Stating specific time limits would not allow the flexibility needed to insure sterility.

Critical elements addressing verification of sheen colonies and conducting the completed test were not intended to increase laboratory work loads. However, many comments suggested that the work load would be increased, especially during the warmer seasons. The critical element relating to verification of sheen colonies is to be applied only to those samples which are determined to be unsatisfactory (presence of five or more sheen colonies). Also, conducting the completed test is applied only to those analyses showing three or more postive tubes. This provides a mechanism by which false positive results can be corrected and water systems will not be reported to be in non-compliance in an official report. Adjustment of coliform data can be based only upon verified colonies or completed test results; however, the initial reporting of unsatisfactory samples should be based upon unverified MF and confirmed test MPN data. Therefore, verification of sheen colonies and conducting completed tests will not delay action response to laboratory findings. It is important to remember that these critical elements apply only to samples initially determined to be unsatisfactory. The work load will increase only if corrective action is not taken to upgrade the water systems.

Critical elements that relate to sample transit time were not changed because sufficient data is not yet available to justify making the sample transit/storage time more stringent. However,

States having primacy can require a transit time which is more stringent than the federal guidelines based upon specific needs.

The test for bacteriological quality of distilled water (distilled water suitability test) also remains as a critical element. Other tests, such as the "Interval Plating Procedure" and the "Use Test" were considered as alternatives. However, based upon reviewer comments and the lack of sufficient data to demonstrate that the alternate tests are comparable or better than the distilled water suitability test, the distilled water suitability test was retained.

It is recognized that personnel and laboratory facilities are critical to the best application of methodology which assures obtaining valid data: however, there are no critical elements relating to Personnel and Laboratory Facilities in the revised chapter. In fact, there were no minimum requirements proposed in the interim certification manual. During the course of the revision, critical elements were suggested relating to academic training, on-job-training, and experience for both the analyst and supervisor or consultant. Also, critical elements relating to laboratory facilities were suggested. State laws and regulations pertaining to personnel and facilities vary so greatly among the States that any critical element acceptable to all State programs would be ineffectual. Each State can better address the needs pertaining to personnel and facilities based upon the individual State laws and regulations. However, guidelines are given in the Recommended Practices section of the revised manual relating to both personnel and facilities.

Time does not permit discussion of every critical element. Reviewer comments were used to determine which items would be included in the Critical Elements for Certification section and all of the critical elements are considered minimal. Only the critical elements are to be used to determine certification approval. Recommended Practices are guidelines used to assist in overall good laboratory practices. States having primacy can make critical elements more stringent or include additional critical elements in accordance with State programs.

During the course of the Microbiology Chapter revision, the Subcommittee recognized additional needs based upon reviewer comments. Therefore, the Subcommittee recommended that the DWLCI Work Group consider three additonal proposals. (1) That an official central clearinghouse be designated by the DWLCI Work Group to respond to technical questions from both Regions and States concerning laboratory evaluations. This clearinghouse could also provide guidance as to how critical elements are applied to determine certification approval, hopefully, assuring more uniformity of the overall certificaation program. For example, would determination of non-compliance for a single critical element result in a recommendation for certification disapproval? (2) The certification program should function so that the evaluators are qualified to provide technical assistance to those laboratories experiencing difficulties rather than functioning solely for certification. (3) The regional laboratory evaluators should meet annually to exchange viewpoints, discuss problems and propose needed changes to insure uniformity relating to evaluations. Input from evaluators will be of particular benefit for future revision and updating of the certification manual. These recommendations appear even more important now that the EPA National Training and Operational Technology Center has been abolished.

In summary, the revised Microbiology Chapter was basically a format revision. The chapter was reorganized into three sections with the Critical Elements for Certification section listing all items, including quality control items, to be applied to the evaluation of laboratories involved in analyzing public drinking water. Drafts of the revision were submitted for extensive review and all comments received were considered in preparation of the revised chapter. A sincere effort was made not to include additional critical elements which were not initially in the mannual for interim certification. Future revisions will be necessary in order to update and improve critical elements. These revisions will reflect the needs of laboratories and the certification program based upon additional data and recommendations of those involved in the program.